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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,046	01/12/2001	Edith Mathiowitz	BU 111	1885
23579	7590	04/27/2004	EXAMINER	
PATREA L. PABST HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET, N.E. ATLANTA, GA 30309-3400			PAGE, THURMAN K	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/760,046	Applicant(s) MATHIOWITZ ET AL.	
	Examiner Thurman K. Page	Art Unit 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 04 April 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1,3,4,6-13,15-26 and 34.

Claim(s) withdrawn from consideration: none.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: _____

Thurman K. Page
SPE
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Continuation of 2. NOTE: The claims as examined require that the process present steps that make dry micronized particles of an agent. The proposed claims now suggest that an additional step (e) be added to avoid the 102 rejection given in the first office action. Note that examined original claim 2 specifically requires the separation of two solids. The proposed additions would require further reconsideration and search for step(e), not previously presented.

Applicant's remarks against Shah are therefore not convincing since the distinctions advanced for the presence of a double emulsion would not be precluded by applicant's comprising claims. Arguments advanced against Shah for the absence of limitations are not persuasive since the generic claims fail to present these limitations in claim language to demonstrate criticality. The generic claims do not require a protein, peptide or drug agent. Hence, this argument would not be persuasive. The particle size limitation presented in the specification indicate no criticality in the particle size but does mention a desirability of certain particle size distribution ranges no criticality being discussed. This distribution range is not being claimed, except for claim 6 which presents the entire range well known in the prior art, as admitted by applicant at the paragraph bridging pages 1 and 2 et seq. Since Shah discloses microparticles the burden would shift to applicant to establish some criticality in a preferred range being claimed. The instant specification does not establish criticality.

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